


August 29, 2011
Wilmington, Delaware.


Stark, District Judge:

I. INTRODUCTION

In this Hatch-Waxman action, plaintiffs Alza Corporation and Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Plaintiffs") filed a complaint against Defendants Kremers Urban, LLC and Kudco Ireland Ltd. ("Defendants") on January 8, 2010. (D.I. 1) Plaintiffs allege that Defendants infringe U.S. Patent No. 6,930,129 ("the '129 patent"). (*Id.*) Presently before the Court is the matter of claim construction. Briefing on claim construction was completed on February 4, 2011. (D.I. 63; D.I. 65; D.I. 79; D.I. 80) The Court held a claim construction hearing on February 24, 2011. *See* Claim Construction Hr'g Tr., Feb. 4, 2011 (D.I. 94) (hereinafter "Tr."). The meaning of one term appearing in all the claims of the '129 patent is disputed.

II. LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in

question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be

read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court also may rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the

purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

III. DISCUSSION

The claim construction dispute at bar centers on one issue: whether the claims of the ’129 patent cover only once-a-day, single administration treatments, or whether they also cover multiple dose treatments. Plaintiffs argue that the claims are limited to once-a-day administration, while Defendants argue that no such limitation is warranted. Although the evidence on both sides is persuasive, the Court finds that the intrinsic evidence as a whole favors Plaintiffs’ position. Accordingly, the Court will construe the claims of the ’129 patent as limited to once-a-day administration.

The ’129 patent contains ten claims directed to a treatment for Attention-Deficit Disorder (“ADD”) and Attention-Deficit Hyperactivity Disorder (“ADHD”). Claim 1 states:

1. A method for treating Attention-Deficit Disorder or Attention-Deficit Hyperactivity Disorder in a patient, wherein the method comprises administering a pharmaceutically acceptable composition comprising methylphenidate and a pharmaceutically acceptable carrier to said patient in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a time period of about 8 hours following said administration.

(’129 patent col.23 ll.12-19) Independent Claim 2 is identical to Claim 1, but changes the “time period” to “about 9.5 hours following said administration.” Claims 3-6 depend on Claim 1 and add limitations specifying that “said composition comprises” a certain amount of methylphenidate: 14 mg, 18 mg, 36 mg, and 54 mg, respectively. Claims 7-10 depend on Claim 2 adding the identical limitations which Claims 3-6 add to Claim 1.

The parties disagree as to the meaning of the term “administering;” in particular, whether this word should be read as “administering once daily.” On its own, the claim language favors Defendants’ position. There is no express reference in the claims to single dose or once-a-day administration. The claims are silent on the concept of single versus multiple dose treatments – just as they are silent about many things, such as oral versus intravenous administration, child versus adult patients, etc. There is nothing in the text of the claims on which to base a single dose limitation.

Even more, the indefinite article “a” preceding “pharmaceutically acceptable composition” and “manner that achieves” favors Defendants’ construction. In patent claims, the word “a” is generally understood to mean “one or more.” *See KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) (“This court has repeatedly emphasized that an indefinite article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended

claims containing the transitional phrase ‘comprising.’”). This “is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit ‘a’ or ‘an’ to ‘one.’” *Baldwin Graphics Sys., Inc., v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). The Court, thus, finds it more persuasive to read “a pharmaceutically acceptable composition” as “one or more pharmaceutically acceptable compositions” and “a manner that achieves” as “one or more manners to achieve,” both of which favor Defendants’ position.

The claim language from which Plaintiffs implicitly find the limitation to a single dose is unpersuasive. Plaintiffs emphasize that the claims list only one administration step, thus arguing that only a single dose is contemplated. This single step, however, encompasses multiple dose treatment since, as described above, “one or more pharmaceutically acceptable compositions” can be administered. Plaintiffs also point to the term “said administration” at the end of Claims 1 and 2, which they argue indicates that a single administration step is mandated. But this “administration” refers to the same administration of “one or more pharmaceutically acceptable compositions.” Likewise, “said composition” in the dependent claims refers to the “one or more pharmaceutically acceptable compositions” of the independent claims. Therefore, again, the claim language favors Defendants’ position.

This conclusion, however, is not dispositive. The Court will consider all of the intrinsic evidence to determine the proper construction. Here, the specification has more bearing on the present dispute than do the claims. Claims, of course, “must be read in view of the specification, of which they are a part.” *Phillips*, 415 F.3d at 1315 (internal quotations and citations omitted). While the ’129 patent specification contains persuasive points for both sides, ultimately

Plaintiffs' position finds more support.

As an initial matter, the Court is mindful of the restriction against reading a limitation into a claim from the specification. *See Phillips*, 415 F.3d at 1323. The Court also recognizes that “there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.” *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998); *see also Phillips*, 415 F.3d at 1323 (“[W]e recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice.”). But “interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation,” only the latter which, of course, “is improper.” *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003) (internal quotations and citations omitted). The analysis below reads the claims of the ’129 patent in light of the specification and avoids the “danger of reading in limitations from the specification into the claims.” *Phillips*, 415 F.3d at 1323.

The Court will construe the claim term “administering” to mean “administering once daily.” *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005) (“Our case law requires a textual ‘hook’ in the claim language for a limitation . . . to be imposed. Generally, a party wishing to use statements in the written description to confine or otherwise affect a patent’s scope must, at the very least, point to a term or terms in the claim with which to draw in those statements.”). The following portions of the specification favor this construction. The written description, in the Background of the Invention, first describes a problem experienced with certain therapies using “constant-release dosage forms,” which are dosage

forms that generate a plasma drug concentration which “remains substantially constant over an extended period as drug release continues at a constant rate.” (’129 patent col.3 ll.2-4). The patent states:

Although constant-release dosage forms have proven effective for many different drug therapies, there are clinical situations where these have not been entirely satisfactory. It has been observed that for some patients being treated with constant-release dosage forms for some conditions or diseases, the therapeutic effectiveness of the drug decreases at time periods before the end of the desired therapy period despite the maintenance of substantially constant drug release that would be expected to provide continued effectiveness. Accordingly, there remains a need to provide methods and devices for maintaining a desired therapeutic drug effect over a desired prolonged therapy period when sustained-release dosage forms that release drug at a substantially constant rate over an extended time period are not satisfactory.

(*Id.* col.3 l.60 - col.4 l.7)

This need, the patent indicates, is addressed by the patented method. The Brief Summary of the Invention states that it was “surprisingly discovered that, in an exemplary clinical situation, administration of drug at a release rate that is ascending, rather than substantially constant, over an extended time period provided therapeutic efficacy that did not decrease before the end of the prolonged therapy period.” (*Id.* col.4 ll.14-19) The patent thereby makes clear that ascending release rates overcame the shortcoming of the prior art. The Brief Summary of the Invention next explains that, upon this discovery, “a need arises for sustained-release oral dosage forms adapted to provide such a release rate over a suitable extended time period” (*id.* col.4 ll.22-24), and the patent goes on to describe numerous discovered dosage forms that have the necessary characteristics. After a lengthy description of dosage forms, the patent states that there “are

numerous clinical situations and drug therapies that could be improved” with the patented method (*id.* col.5 ll.27-30), and thirty-seven different drug types are listed (*see id.* col.5 ll.34-46).

The patent then states:

The exemplary clinical situation described herein involves treatment of ADHD with methylphenidate therapy. Accordingly, the present invention also pertains to making oral methylphenidate sustained release dosage forms that provide a sustained and ascending release rate of a drug over an extended time period.

It has further been discovered that oral methylphenidate sustained release dosage forms that provide an ascending release rate of a drug over an extended time period can be used to provide effective once-a-day therapy for ADHD. ***Thus, the present invention also pertains to improving drug therapy for ADHD by eliminating the need for multiple daily doses of methylphenidate yet providing therapeutic efficacy throughout the day that compares to the therapeutic efficacy provided by multiple doses of immediate release methylphenidate.***

(*Id.* col.5 ll.48-63) (emphasis added)

The next section, the Detailed Description of the Invention, echoes the shortcoming of the prior art discussed in the Brief Summary (*see id.* col.6 ll.48-52), and then focuses specifically on the treatment of ADD and ADHD, which is an “example of a clinical situation where drug therapy with sustained-release oral drug dosage forms that provide a substantially constant rate of drug release for an extended period has not been entirely satisfactory” (*id.* col.6 ll.53-56). The patent discusses specific hardships associated with the treatment of ADD and ADHD using the drug methylphenidate:

Treatment commonly utilizes immediate-release methylphenidate administered two or three times during the day. For various

reasons, patients often experience difficulty complying with this administration schedule. Because of abuse potential, methylphenidate is a controlled substance and thus drug access is a special concern. This dosage regimen generally requires that at least one dose is administered during the school day and, as a rule, children are not permitted to self-administer the drug at school. For this reason, authorized school personnel generally take on the responsibility for administering the drug to children during the school day, however, this approach raises issues of medical privacy and potential stigmatizing of the child by peers. In addition, the compliance issue becomes further complicated as transportation, storage and supply of the drug typically must be documented and/or monitored and the schedules of the different parties involved, i.e., the child, the educators and the authorized school personnel, must be coordinated and accommodated. The unfortunate result is that doses may be given late or missed altogether resulting in decreased efficacy of the therapy.

(*Id.* col.7 ll.14-34) The patent thus explains that there is an even greater need for the patented method in the treatment of ADD and ADHD: “For all of the above reasons, it would appear that a sustained-release oral dosage form of methylphenidate that provided substantially constant drug release over an extended period to thereby eliminate the need for dose administration during the school day would be a welcome improvement.” (*Id.* col.7 ll.35-40)

The patent goes on to explain that a sustained-release product for treating ADD and ADHD is commercially available but “has been disappointing in that behavioral symptoms in patients taking the controlled-release dosage form is less well-controlled later in the day compared to those patients taking multiple doses of the immediate-release dosage form. In addition, the slower onset of action of the controlled-release dosage form compared to the immediate-release dosage form is unsatisfactory for many patients.” (*Id.* col.7 ll.42-48) The specification describes the “surprising discovery” of the patented method specifically with

regards to methylphenidate: administration at an ascending release rate proved more effective than administration at a constant release rate. (*See id.* col.7 ll.50-55, *id.* col.6 ll.10-16, 28-30) The patent gives a lengthy description of discovered dosage forms which provide an ascending release rate. (*See id.* col.8 l.31 - col.13 l.39) In this description, eight examples are introduced which are embodiments of the patented dosage forms. (*See id.* col.11 ll.51-52; *id.* col.13 ll.36-39) The patent also introduces an example, Example 7, which tested and showed the therapeutic effectiveness of an oral osmotic dosage form containing methylphenidate that produces an ascending release rate. This descriptions restates what was described earlier:

[I]t has been discovered that such osmotic dosage forms containing methylphenidate [i.e., those which “exhibit an ascending release rate over an extended time period” (col.13 ll.43-44)] can be used to provide effective once-a-day therapy for ADHD. ***This discovery represents an important improvement in drug therapy for ADHD by eliminating the need for multiple daily doses of methylphenidate yet providing therapeutic efficacy throughout the day that compares to the therapeutic efficacy provided by multiple doses of immediate release methylphenidate.***

(*Id.* col.13 ll.46-54) (emphasis added) Finally, in the description of Example 7, the patent states:

The clinical effectiveness of the experimental regimen [i.e., single doses of tri-layer osmotic dosage forms containing 14 mg of methylphenidate and additionally comprising an immediate-release drug overcoat containing 4 mg of methylphenidate] was closely comparable to the clinical effectiveness of the standard regimen [i.e., multiple doses of immediate-release methylphenidate] throughout the twelve-hour study period. ***An effective once-a-day therapy for ADHD provides many advantages and offers a significant improvement in drug therapy by eliminating the need for multiple daily doses of methylphenidate while providing continued therapeutic efficacy throughout the day.***

(*Id.* col.22 ll.19-27) (emphasis added)

Hence, the patent makes at least three references to the problems associated with multiple dose treatment of ADD and ADHD and, in this way, teaches away from multiple dose administration of immediate-release methylphenidate. The patent also emphasizes the need that existed for an effective once-a-day treatment of ADD and ADHD, which was unresolved by the prior art sustained-release methylphenidate treatment. According to the patent, this need was satisfied by the claimed method. It would be problematic to construe the asserted claims in a manner that would bring the distinguished prior art methods within their scope. *See Kinik Co. v. Int'l Trade Comm'n.*, 362 F.3d 1359, 1365 (Fed. Cir. 2004) (“Claims cannot be construed as encompassing the prior art that was distinguished in the specification and disclaimed during prosecution.”); *SciMed Life Sys. v. Advanced Cardiovascular*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (“Thus, the SciMed patents distinguish the prior art . . . and point out the advantages of the [devices]. . . that are the subjects of the SciMed patents. That discussion in the written description supports the district court’s conclusion that the claims should not be read so broadly as to encompass the distinguished prior art structure.”). While portions of the specification discussed below preclude a finding of a clear disavowal of multiple dose administration, nonetheless the portions of the specification cited above strongly support Plaintiffs’ construction. *See Astrazeneca AB v. Mutual Pharm.*, 384 F.3d 1333 (Fed. Cir. 2004) (“Where the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that same feature, this operates as a clear disavowal of these other products (and processes using these products).”) (citing *Scimed*, 242 F.3d at 1340-45).

Defendants argue that construing the claims to cover only single dose administration

commits the “cardinal sin” of limiting the claims to a preferred embodiment, specifically to the embodiment disclosed in Examples 6 and 7. But when the claims are construed in light of the specification, numerous embodiments are still within their scope. While one aspect of the claimed method is limited – “administering” covers only once-daily administration – there is broad breadth in other aspects of the claims, such as the covered dosage forms. In the specification alone, eight different dosage forms are disclosed in Examples 1-6 and 8-9, all of which are covered by the claims as construed by the Court.

Admittedly, there are portions of the written description which favor Defendants’ position. First, there is no explicit disclaimer of multiple dose treatments in the patent, although the criticisms of the prior art discussed above come close. Second, the Brief Summary of the Invention emphasizes the breadth of the invention (*see* ’129 patent col.4 l.10- col.6 l.14), and makes clear that the invention covers any dosage form that produces an ascending release rate of any medication, not just methylphenidate, to treat any condition, not just ADD and ADHD (*see id.*). In fact, once-a-day treatment of ADD and ADHD is not mentioned until the tenth paragraph of this section, where it states that “the present invention also pertains to improving drug therapy for ADHD by eliminating the need for multiple daily doses of methylphenidate,” making plain that the patentee believed it had invented this as well as at least something else. (*Id.* col. 5 ll.58-60) The impact of this observation, however, is minimized by the Detailed Description of the Invention, which is primarily dedicated to treatment of ADD and ADHD with methylphenidate using the patented method. The following excerpt favoring Defendants’ position also appears in the Brief Summary of the Invention:

Although the present invention is illustrated herein by exemplary dosage forms containing specific exemplary drugs, methods of making such dosage forms and methods of using methylphenidate-containing dosage forms to provide a desired therapeutic outcome, the invention is not limited by the exemplary embodiments. The invention broadly embraces oral sustained-release dosage forms that provide an ascending drug release rate over an extended time period, methods of making such dosage forms and methods of using such dosage forms to maintain therapeutic effectiveness for a desired prolonged therapy period with respect to any appropriate drugs and drug therapies as would be apparent to a person of skill in the art in view of the disclosure herein.

(*Id.* col.6 ll.1-14) This emphasis on the breadth of the invention favors the argument against restricting the scope of the claims, but the claims themselves – which pertain specifically to ADD and ADHD treatment using methylphenidate – minimize the effect of this excerpt, which is to some extent “boilerplate” present in many patents.

The portion of the written description which most favors Defendants’ position is the following:

The amount of drug incorporated in the dosage forms of the present invention varies depending on the particular drug, the therapeutic indication and the desired administration period, e.g., every 12 hours, every 24 hours, etc. Depending on the dose of drug desired to be administered, one or more of the dosage forms may be administered.

(*Id.* col.9 ll.15-20) Consistent with the other portions of the specification that emphasize the breadth of the invention, this excerpt indicates that the number and frequency of dosages can vary depending on the treatment situation. This supports a refusal to limit the claims to only a single administration period.

Defendants also rely on a portion of the written description which they argue shows that “administration” can refer to multiple doses:

The selected times corresponded to the time just prior to, and 1.5 hours and 2.5 hours following, administration of the first two doses of immediate-release methylphenidate (i.e., at $t=0$ hours, $t=1.5$ hours, $t=2.5$ hours, $t=4$ hours, $t=5.5$ hours, $t=6.5$ hours), and just prior to, and 1.5 hours and 3.5 hours following, administration of the third dose (i.e., at $t=8$ hours, $t=9.5$ hours and $t=11.5$ hours).

(*Id.* col.21 ll.48-54) The Court, however, finds the best reading of this excerpt is that “administration” refers to the administration of a single dose, three of which are described, occurring at $t=0$, $t=4$, and $t=8$ respectively. “Administration” does not collectively refer to all three of these doses.

Finally, the Court has considered the prosecution history on which Defendants rely but does not find it especially compelling. Specifically, Defendants point to a cancelled claim submitted during prosecution of the ’129 patent’s parent patent, U.S. Patent No. 6,919,373. The claim read:

A method of compensating for a decrease in therapeutic effect of methylphenidate in a patient being treated with multiple doses over a prolonged period, the method comprising orally administering one dose of a dosage form table comprising 100 ng to 500 mg of methylphenidate that delivers the methylphenidate at an ascending release rate for an extended period of time.

(D.I. 63 Ex.5 at 3) To the extent that this claim bears on the instant dispute, the Court finds it favors Plaintiffs’ position. The cancellation of a claim during prosecution of a related patent, which expressly called out the single dose limitation (and would more precisely accomplish the

construction Plaintiffs advocate here), does not clearly indicate that different coverage was sought by an issued claim that was worded differently. Similar coverage can exist between two issued claims; so, too, may an issued claim and a cancelled claim have similar scope. See *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (“[C]laim drafters can also use different terms to define the exact same subject matter. Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter.”). Also, the cancelled claim uses the term “multiple doses,” which indicates the claim drafter knew how to refer to multiple dose administration explicitly; the claims at issue do not use this terminology to describe the patented treatment method.

In sum, while the claim language favors Defendants’ position, the remainder of the specification favors Plaintiffs’ position, although certain portions do support Defendants’ position; the prosecution history is of little help but favors Plaintiffs’ position.

IV. CONCLUSION

For the reasons stated above, “administering,” as it appears in Claims 1-10 of the ’129 patent, will be construed as “administering once daily.”